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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,628	03/09/2001	William J. Curatolo	PC8626CMAS	7884
7590	06/30/2004		EXAMINER	
Gregg C. Benson Pfizer Inc. Patent Department, MS 4159 Eastern Point Road Groton, CT 06340			GEORGE, KONATA M	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/803,628	CURATOLO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Konata M. George	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                | Paper No(s)/Mail Date: _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                                    |

Continuation of Disposition of Claims: Claims pending in the application are 149,150,152,164,165,168,169,171-176,178,179,182,185,187,189,208,210,212 and 215-220.

Continuation of Disposition of Claims: Claims rejected are 149,150,152,164,165,168,169,171-176,178,179,182,185,187,189,208,210,212 and 215-220.

Art Unit: 1616

### **DETAILED ACTION**

Claims 149, 150, 152, 164, 165, 168, 169, 171-176, 178, 179, 182, 185, 187, 189, 208, 210, 212 and 215-220 are pending in this application.

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on September 26, 2003 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

### ***Action Summary***

2. Examiner acknowledges the cancellation of claims 151, 153-163, 166, 167, 170, 177, 180, 181, 183, 184, 186, 188, 190, 209 and 211. Therefore, any and all rejections directed towards them is hereby withdrawn.
3. The rejection of claims 149, 150, 152, 164, 165, 168, 169, 171-176, 178, 179, 182, 185, 187, 189, 210, 212 and 214 under 35 U.S.C. 103(a) over Curatolo et al. in view of Morishita et al. is hereby withdrawn.

### ***Claim Objections***

4. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims

Art Unit: 1616

are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 213-218 been renumbered 215-220.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 149, 150, 152, 164, 165, 168, 169, 171-176, 178, 179, 182, 185, 187, 189, 208, 210, 212 and 215-220 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (USP 5,605,889) in view of Urquhart et al. (USP 4,851,231).

Curatolo et al. teaches a dosage form of azithromycin which can be administered to a mammal. The azithromycin (a compound derived from erythromycin A, see column 1, lines 11-13) can be in various forms such as a pharmaceutically acceptable salt, anhydrous or hydrous, or as a dihydrate and are formulated from about 25 mg to about 3 grams (col. 4, lines 51-61). Column 2, lines 45-54 teach that the composition can be administered as a tablet or in unit dosage packets "sachet" comprising the azithromycin and a pharmaceutically acceptable carrier. Column 6, lines 62-67 teach the use of binders such as cellulose derivatives. It is taught in column 8, lines 19-27 that the drug

could be formulated into a powder for the purposes of making oral suspensions.

Column 7, lines 61-64 teach that a coating can be employed. The prior art does not teach the dosage form being delivered to the gastrointestinal tract as claimed. It is also not taught the dosage form comprising a plurality of microparticles.

Urquhart et al. discloses a system for delivering drug in selected environment of use. Column 1, lines 38-41 teaches drugs where administration to the stomach should be avoided, in line 40 is disclosed antibiotics such as erythromycin. Column 5, lines 47-62 describe FIG. 5 as comprising individual tiny reservoirs comprising a core of beneficial agent, surrounded by a wall formed by a release rate material. It is also taught that the reservoirs may contain one or more layers. Column 7, lines 26-51 disclose exemplary materials of which can be used in the release rate controlling material. Column 8, line 5 teaches that erythromycin can be used in the dosage form. Lines 34-47 of column 8 teaches that the amount of drug that can be used is about 10 ng to 25 mg and the diameter of the tiny reservoirs can be about 100 microns to about 2000 microns.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Urquhart in the invention of Curatolo et al. to disclose the claimed invention. Urquhart teaches a formulation for the administration of drugs in selected environments where delivery to the stomach should be avoided and Curatolo et al. teaches a dosage form of azithromycin. The expected result would be a controlled release dosage form of azithromycin wherein the azithromycin is delivered into the gastrointestinal tract of the human.

***Response to Arguments***

6. Applicant's arguments with respect to claims 149, 150, 152, 164, 165, 168, 169, 171-176, 178, 179, 182, 185, 187, 189, 208, 210 and 212 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

7. 149, 150, 152, 164, 165, 168, 169, 171-176, 178, 179, 182, 185, 187, 189, 208, 210, 212 and 215-220 are rejected.

***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (571) 272-0602. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Application/Control Number: 09/803,628  
Art Unit: 1616

Page 6

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Konata M. George  
Patent Examiner  
Art Unit 1616